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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/659,643	09/12/2000	James J. Gibbons Jr.	AM100081	6975

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EXAMINER	
JONES, DWAYNE C	
ART UNIT	**PAPER NUMBER**
1614	

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/659,643	GIBBONS JR. ET AL.	
	Examiner	Art Unit	
	Dwayne C Jones	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *8-14* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Claims 1-14 are pending.

2. Claims 1-7 are elected and rejected.

3. Claims 8-14 are non-elected and withdrawn from consideration.

Election/Restrictions

4. Applicant's election with traverse of the election of May 12, 2003 in Paper No. 9 for claims 1-7 is acknowledged. The traversal is on the ground(s) that the inventions should be searched together. This is not found persuasive because the inventions of Groups I and II are in fact directed to different effects that are thus independent and distinct. Accordingly, non-elected claims 8-14 are withdrawn from consideration.

5. In addition, the elected species, [R-(R*,R*)]-N-[-(R)-6-carboxy-N2-[[2-carboxy-1-methyl-2-[(1-oxoheptyl)amino]ethoxycarbonyl]-L-lysyl]-alanine was found in the prior art and accordingly rejected.

6. The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

7. The information disclosure statement filed December 12, 2000 and August 2, 2001 fail to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information, submitted for consideration by the Office. It has been

placed in the application file, but the information referred to therein has not been considered.

8. The information disclosure statement filed December 12, 2000 and August 2, 2001 fail to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the term/phrase bioresponse modifier and cytokine inducer. In addition, the instant specification does not describe what is meant by the term/phrase bioresponse modifier and cytokine inducer other than the compounds of formula I. Structural identifying characteristics of the term/phrase bioresponse modifier and cytokine inducer are not disclosed except for those the compounds of formula I. There is no evidence that there

is any per se structure/function relationship between the term/phrase bioresponse modifier and cytokine inducer other than those disclosed, namely the compounds of formula I. The instant specification does provide an adequate written description for the term/phrase of bioresponse modifier and cytokine inducer. Accordingly, these claims fail to comply with the written description requirement.

11. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is insufficient descriptive support for the phrase "treating solid tumor". In addition, the instant specification does not describe what is meant by the phrase "treating solid tumor" other than the treatment of non small cell type lung tumor because the instant specification only provides an adequate written description of treating non small cell type lung cancer with the compound of claim 5, (see pages 5 –7 of the instant specification). Structural identifying characteristics of the phrase "treating solid tumor" are not disclosed except for those the treatment of non small cell type lung tumors. There is no evidence that there is any per se structure/function relationship between the phrase "treating solid tumor" other than those disclosed, namely the treatment of non small cell type lung tumors. The instant specification does provide an adequate written description for the phrase "treating solid tumor". Accordingly, these claims fail to comply with the written description requirement.

Claim R jections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayral-Kaloustian et al. of U.S. Patent No. 5,545,662 in view of The Merck Index. Ayral-Kaloustian et al. teach that the urea and urethane compounds of Formula I are useful in

the treatment of cancer, (see abstract). In addition, Ayral-Kaloustian et al. teach that these compounds are useful for their ability to induce cytokine formation and restore bone marrow after chemotherapy, (see column 17, lines 8-10). Ayral-Kaloustian et al. further teach that the compounds of Formula I are useful in the treatment of cancer, (see column 19, lines 18-31). The Merck Index teaches of the following known anticancer agents: bleomycins, cisplatin, mitomycins, vinblastine, vincristine, (see pages 183, 329, 890-891, and 427-1428, respectively). The skilled artisan would have been motivated to select any known anticancer agent, such as paclitaxol, to treat cancer especially to obviate multi-drug resistance as well as decrease the toxicity level of a chemotherapeutic agent. Moreover, "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Accordingly, the skilled artisan would have been motivated to combine two pharmaceuticals, which are known to treat the very same ailment, namely cancer, together.

16. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent No. 5,545,662 in view of The Merck Index.

17. The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome

by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). As cited above in paragraphs 12 and 13.

Obviousness-type Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 5,545,662 in view of The Merck Index. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 5,545,662 teaches that the urea and urethane compounds of Formula I are useful in the treatment of cancer, (see abstract). In addition, U.S. Patent No. 5,545,662 teaches that these compounds are useful for their ability to induce cytokine formation and restore bone marrow after chemotherapy, (see column 17, lines 8-10). U.S. Patent No. 5,545,662 further teaches that the compounds of Formula I are useful in the treatment of cancer, (see column 19, lines 18-31). The Merck Index teaches of the following known anticancer agents: bleomycins, cisplatin, mitomycins, vinblastine, vincristine, (see pages 183, 329, 890-891, and 1427-1428, respectively). The skilled artisan would have been motivated to select any known anticancer agent, such as paclitaxol, to treat cancer especially to obviate multi-drug resistance as well as decrease the toxicity level of a chemotherapeutic agent. Moreover, "[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. . . .[T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Accordingly, the skilled artisan would have been motivated to combine two pharmaceuticals, which are known to treat the very same ailment, namely cancer, together.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER

Tech. Ctr. 1614
August 18, 2003